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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 1210/69014-B/GJG

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on May 10, 2007

Signature: Gary J. Gershik

Typed or printed name: Gary J. Gershik

Application Number	Filed
10/768,566	January 29, 2004

First Named Inventor: Kiran K. Chada et al.

Art Unit	Examiner
1646	G. Chandra

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [X] attorney or agent of record. Registration number 39,992
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Gary J. Gershik
Signature

Gary J. Gershik
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212-278-0400
Telephone number

May 10, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of _____ forms are submitted.

Docket No. 1210/69014-B/GJG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Kiran K. Chada et al.

Serial No.: 10/768,566 Examiner: G. Chandra

Filed : January 29, 2004

For : METHODS OF TREATING OBESITY AND METABOLIC DISORDERS RELATED TO EXCESS ADIPOSE TISSUE BY ADMINISTRATION OF S-FRP-5 PEPTIDE

1185 Avenue of the Americas
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May 10, 2007

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Pursuant to a July 12, 2005 Notice in the Official Gazette, applicants respectfully request that a Panel of Examiners review the final rejection under 35 U.S.C. § 102 of claims 1, 8, 9, and 17-19, as amended March 9, 2007, in the above-identified application.

This Request is being filed concurrently with a Notice of Appeal in a separate paper.

Issue Presented for Review

In this Request, Applicants request the Panel to consider the issue of whether a claim can be rejected for anticipation under § 102 where the prior art does not disclose every element of the claim, and clearly fails for lack of enablement.

Relevant Facts

For purposes of this Request, the relevant facts are:

1) Applicants have shown in live mice that a certain peptide, named by Applicants "sFRP-5", reduces the amount of adipose tissue (fat) in the mouse as compared to mice fed an identical diet but not sFRP-5. Based on their experiments, Applicants claim a method of reducing the amount of adipose tissue in a subject comprising administering to the subject an amount of an sFRP-5 peptide effective to reduce the amount of adipose tissue, or an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject.

2) The prior art is a single U.S. Patent Application Publication by Xu et al. containing the following paragraph:

> [0018] In yet another aspect, the invention features a method for treating a subject having a metabolic disorder characterized by aberrant SARP3 polypeptide activity or aberrant SARP3 nucleic acid expression, e.g., obesity, diabetes, anorexia, or cachexia. The method includes administering to the subject a SARP3 modulator, e.g., in a pharmaceutically acceptable formulation or by using a gene therapy vector. Embodiments of this aspect of the invention include the SARP3 modulator being a small molecule, an anti-SARP3 antibody, a SARP3 polypeptide comprising the amino acid sequence of SEQ ID NO:2 or 5 or a fragment thereof, a SARP3 polypeptide comprising an amino acid sequence which is at least 90 percent identical to the amino acid sequence of SEQ ID NO:2 or 5, an isolated naturally occurring allelic variant of a polypeptide consisting of the amino acid sequence of SEQ ID NO:2 or 5, an antisense SARP3 nucleic acid molecule, a nucleic acid molecule of SEQ ID NO: 1, 3, 4, or 6 or a fragment thereof, or a ribozyme.

Applicants will agree for purposes of this discussion that "SARP3" of Xu et al. is equivalent to Applicants' "sFRP-5." A complete discussion of the facts appears on the record.

Analysis

Applicants' claimed method achieves a specific results by requiring specific steps. Xu et al. do not describe a method for achieving Applicants' specific claimed result by performing the specific steps. The Examiner and Applicants agree on the record that Xu et al. do not disclose what their SARP3 peptide does, or how, specifically, one skilled in the art could use the SARP3 peptide. Xu et al. disclose that one could "modulate" SARP3. Precisely what "modulate" means is not disclosed; nor is the consequence of any specific modulation disclosed. Thus, Xu et al. fail to disclose that an increase in the sFRP-5 (SARP3) peptide is needed to reduce adipose tissue.

Accordingly, it was impossible from Xu et al. to envisage Applicants' claimed specific method requiring, a) an increase in sFRP-5 for b) the reduction of adipose tissue. Xu et al. fail to disclose each of elements a) and b), and, more importantly, also fail to disclose the correlation of the two specific elements.[1]

During discussion with Examiner G. Chandra and Supervisory Examiner G. Nickol, the Examiners maintained that Xu et al. disclosed every element of the claim. Even if that was correct, that by itself is insufficient to anticipate an invention in the

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[1]*The March 5, 2007 Advisory Action attempts to circumvent this necessary conclusion by relying on the doctrine of inherent anticipation. Applicants respectfully submit that the doctrine is ill suited for the fact pattern of this case where the prior art never used the peptide in any method. See Applicants' response dated March 9, 2007.*

unpredictable field of biotechnology. Xu et al. would also need to have enabled their disclosure. Clearly, however, Xu et al. do not enable their disclosure. Examiner G. Chandra has eloquently set forth some of the many reasons why Xu et al. fail to enable anything they may describe with respect to SARP3 in a May 16, 2006 Office Action in Xu et al.(U.S. Serial No. 10/338,604).[2] A copy of the May 16, 2006 Office Action from the file history of Xu et al. was made of record in the subject application for this purpose in Applicants' response dated January 26, 2007.

Applicants' claims are patentable over Xu et al., and to hold otherwise would be repugnant to the letter and purpose of the patent law. Accordingly, the Panel should withdraw the rejection based on Xu et al. The holding in *In re Wiggins*, 488 F.2d 538 (CCPA 1973), for example, is instructive:

> The defect in the issue, as stated by the solicitor, is that it presumes that the naming of compounds by [the prior art] constitutes a description of the invention within the meaning of § 102(b). We do not accept this presumption. In our view, [the prior art] listing of the compounds by name constituted nothing more than speculation about their potential or theoretical existence. The mere naming of a compound in a reference, without more, cannot constitute a description of the compound, particularly when, as in this case, the evidence of record suggests that a method suitable for its preparation was not developed until a date later than that of the reference.
>
> If we were to hold otherwise, lists of thousands of theoretically possible compounds could be generated and published which, assuming it would be within the level of skill in the art to make them, would bar a patent to the actual discoverer of a named compound no

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[2] *U.S. Serial No. 10/338,604, Xu et al., is indicated as being abandoned on the PAIR records of the U.S. Patent Office for failure of Xu et al. to reply to Examiner Chandra's May 16, 2006 Office Action.*

> matter how beneficial to mankind it might be. In view of the fact that the purpose sought to be effectuated by the patent law is the encouragement of innovation, such a result would be repugnant to the statute. Therefore, we hold that the compounds named in [the prior art] and within the scope of the claims in issue were not "described in a printed publication" as meant by the applicable portion of § 102(b). (Emphasis added.)

Applicants respectfully request the Panel to withdraw the improper rejection under § 102 in this application.

No fee is deemed necessary in connection with the filing of this Pre-Appeal Brief Request For Review. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450
Alexandria, VA 22313-1450.

Gary J. Gershik 5/10/07
Gary J. Gershik Date
Reg. No. 39,992